

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60118012 0001

Report No.: 31793658 001

Manufacturer: Ferris Mfg. Corp.
5133 Northeast Parkway
Fort Worth TX 76106
USA

Products: Wound Care Dressings


For the following product the scope covers aspects of manufacturing concerned with securing and maintaining sterile conditions:
- Nursicare Breast Pad

Expiry Date: 2022-11-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-11-16

Date: 2017-11-15

Notified Body

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.